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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,567	04/05/2002	Jonathan Richard Anthony Roffey	040283-0196	4959

7590

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EXAMINER

ANDERSON, REBECCA L

ART UNIT

PAPER NUMBER

1626

DATE MAILED: 03/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/009,567	Applicant(s) ROFFEY ET AL.	
	Examiner Rebecca L Anderson	Art Unit 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 December 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14, 17-21, 24-26 and 28-36 is/are pending in the application.
- 4a) Of the above claim(s) 18-21, 26, 32 and 34-36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☒ Claim(s) 1-14, 17, 24, 25, 28-31 and 33 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>1 Dec 2003</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-14, 17-21, 24-26 and 28-36 are currently pending in the instant application. Claims 18-21, 26, 32 and 34-36 are withdrawn from consideration as being for non-elected subject matter and claims 1-14, 17, 24, 25, 28-31 and 33 are objected.

Election/Restrictions

Applicants Petition for the review of the restriction requirement under 37 CFR 1.144 was received on 1 December 2003. A decision has not yet been rendered.

The elected invention with traverse, upon reconsideration as found in the office action mailed 29 September 2003, for search and examination is the product of the formula (I) wherein:

R1-R7 are as found in claim 1 and A is 2,3-dihydrofuryl, a process for the preparation of the product of formula (I) and a method of treatment of disorders of the central nervous system selected from depression, atypical depression, bipolar disorders, anxiety disorders, obsessive-compulsive disorders, social phobias or panic states, sleep disorders, sexual dysfunction, psychoses, schizophrenia, migraine, pain, raised intracranial pressure, epilepsy, personality disorders, age-related behavioural disorders, behavioural disorders associated with dementia, organic mental disorders, mental disorders in childhood, aggressivity, age-related memory disorders, chronic fatigue syndrome, drug and alcohol addiction, obesity, bulimia, anorexia nervosa and premenstrual tension.

In the response filed 1 December 2003, applicant argues that the restriction requirement arbitrarily ignores what the applicants define to be their invention.

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Applicant states that the -N=C-SCH_3 linked to a six atom ring is the significant structural element which is shared by all the alternatives and that all compounds share a common chemical structure, the thiazole ring and the six atom heterocyclic compound bound to an imino group. Applicant also argues that the combination of U.S. Patent No. 5,633,276 and 5,755,829 does not support a finding of a lack of unity of invention and that all of the pending method claims have unity of invention because they are linked by a common structure. This is not found persuasive because, the examiner points out that the structural feature present in the claims is N-aminoethyl indoline which is found in US'276. Although the variables on the N-aminoethyl indoline differ from US'276, they are not considered part of the technical feature present in the instant claims. Therefore, for essentially the same reasons as found in the previous office action, the claims herein lack unity of invention because the structural feature present in the claims is not a significant structural element qualifying as the special technical feature that defines a contribution over the prior art. Also, even if the structural feature present in the claims was the indoline group substituted at its nitrogen atom by an aminoethyl group – $(\text{CH}_2)(\text{CHR}_3)\text{pNR}_1\text{R}_2$, wherein R_3 is alkyl and R_1 and R_2 are H or alkyl, this would still not be considered a special technical feature which describes a contribution over the prior art as US Patent No. 5,755,829 discloses N-substituted 4-hydroxyindoline compounds wherein R_1 can be a (C1-4) aminoalkyl radical in which the amine is nono- or disubstituted by a (C1-4)alkyl group and the (C1-C4) alkyl group can be linear or branched (column 2, lines 5-51). For essentially the same reasons as stated in the prior office action, the lack of unity has been shown by the fact that the technical feature, the

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N-aminoethyl indoline, in common with all of the instant claims is known in the prior art and is therefore not a special technical feature which defines a contribution over the prior art. Furthermore, since the claims lack unity of invention, the examiner may determine the groups of inventions which are so linked as to form a single general inventive concept without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim. In this regard, the MPEP states in section 1850 D, that

wherein a single claim defines alternatives (chemical or non-chemical) is also governed by PCT Rule 13.2. In this special situation, the requirement of a technical interrelationship and the same or corresponding special technical features as defined in PCT Rule 13.2, shall be considered to be met when the alternatives are of a similar nature.

When the Markush grouping is for alternatives of chemical compounds, they shall be regarded as being of a similar nature where the following criteria are fulfilled:

- (A) All alternatives have a common property or activity; and
- (B) (1) A common structure is present, i.e., a significant structural element is shared by all of the alternatives; or
- (C) (2) In cases where the common structure cannot be the unifying criteria, all alternatives belong to a recognized class of chemical compounds in the art to which the invention pertains

The alternatives in A do not have a common property or activity as a 2,3-dihydrofuryl group is not expected to react in the same way as a phenyl group. The alternatives also do not share a common structure, i.e. there is not common structure between 2,3-dihydrofuryl and a 6 membered carbocyclic ring, etc., and the alternatives do not belong to a recognized class of chemical compounds in the art to which the invention pertains, specifically, the classification of a furyl group or a phenyl group, etc. differs in the US classification system. Finally, in regards to the method of treatment claims, for essentially the same reasons as stated in the prior office action, it is stated that the

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structural feature that found in all the claims is the N-aminoethyl indoline which is not a special technical feature that defines a contribution over the prior art of record and therefore the claims lack unity of invention. Furthermore, claims to different categories of invention are considered to have unity of invention if the claims are drawn only to one of the combinations listed in 37 CFR 1.475(b).

The requirement is still deemed proper and is therefore made FINAL.

This application contains claims 18-21, 26, 32 and 34-36 drawn to an invention nonelected with traverse in the response filed 7 July 2003. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Maintained Claim Objections

Claims 1-14, 17, 24, 25, 28-31 and 33 are objected to for containing non-elected subject matter.

The remaining subject matter of claims 1-14, 17, 24, 25, 28-31 and 33 and the subject matter of claims 18-21, 26, 32 and 34-36 that is not drawn to the above elected groups stands withdrawn as being for non elected subject matter. The remaining compounds and methods which are not within the elected group, which are independent

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and distinct from the elected group and do not have unity with the elected group because the technical feature present in the instant claims is not a special technical feature which defines a contribution over the prior art and are withdrawn from consideration. Compounds which are withdrawn by means of a restriction requirement are the compounds, for example, wherein: A is , cyclohexenyl, cyclopentenyl, phenyl, dihydropyranyl, dihydrothienyl, tetrahydropyridinyl, 2,3-dihydro-1,4-dioxin, etc., and methods of treatment of damage to the central nervous system by trauma, stroke, neurodegenerative diseases or toxic or infective CNS diseases such as encephalitis or meningitis, thrombosis, gastrointestinal disorders such as gastrointestinal motility, diabetes insipidus, sleep apnea and conditions treatable by agonism of the 5HT₂ receptor except for depression, atypical depression, bipolar disorders, anxiety disorders, obsessive-compulsive disorders, social phobias or panic states, sleep disorders, sexual dysfunction, psychoses, schizophrenia, migraine, pain, raised intracranial pressure, epilepsy, personality disorders, age-related behavioural disorders, behavioural disorders associated with dementia, organic mental disorders, mental disorders in childhood, aggressivity, age-related memory disorders, chronic fatigue syndrome, drug and alcohol addiction, obesity, bulimia, anorexia nervosa and premenstrual tension, and methods of preventing disorders of the central nervous system, damage to the central nervous system, cardiovascular disorders, gastrointestinal disorders, diabetes insipidus, sleep apnea, etc.

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Some specific species of the withdrawn compounds are the species of .(S)-1-(benz[g]indolin-1-yl)-2-propylamine, (S) -1-(2,3,7,8-tetrahydrothieno[2,3-g]indol-1-yl)-2-propylamine, etc.

Claims 1-14, 17, 24, 25, 28-31 and 33 drawn solely to the elected invention identified supra would appear allowable over the prior art of record.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rebecca L. Anderson whose telephone number is (571) 272-0696. Mrs. Anderson can normally be reached Monday through Friday 5:30AM to 2:00PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Mr. Joseph McKane, can be reached at (571) 272-0699.

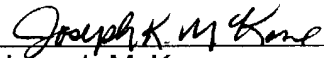
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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone numbers are (703) 308-1235 and (703) 308-0196.

A facsimile center has been established. The hours of operation are Monday through Friday, 8:45AM to 4:45PM. The telecopier number for accessing the facsimile machine is (703) 872-9306



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